UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ABBOTT LABORATORIES and ABBOTT BIOTECHNOLOGY LIMITED, Plaintiffs, v. THE MATHILDA AND TERENCE KENNEDY INSTITUTE OF RHEUMATOLOGY TRUST, Defendant.	Civil Action No.: 11-cv-2541 (PAC) ECF Case **JURY TRIAL DEMANDED**

DEFENDANT'S ANSWER AND FIRST AMENDED COUNTERCLAIMS

Defendant The Mathilda and Terence Kennedy Institute of Rheumatology Trust ("Kennedy") hereby submits its Answer to the Complaint of Plaintiffs Abbott Laboratories and Abbott Biotechnology Limited and Counterclaims, as follows:

Kennedy denies Plaintiffs' characterization of "Kennedy's assertions" as set forth in the introductory unnumbered paragraph to the Complaint. Kennedy's initial communications concerning U.S. Patent No. 7,846,442 ("the '442 patent") are set forth in a letter dated January 26, 2011 from counsel for Kennedy.

NATURE OF ACTION

1. Paragraph 1 is a conclusion of law to which no response is required. To the extent that a response is required, Kennedy denies the allegations of Paragraph 1 of the Complaint.

THE PARTIES

2. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint, and on that basis denies those allegations.

3. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the allegations of Paragraph 3 of the Complaint, and on that basis denies those allegations.

4. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the allegations of Paragraph 4 of the Complaint, and on that basis denies those allegations.

5. Kennedy admits the allegations of Paragraph 5 of the Complaint.

6. Kennedy admits that since 2002, Abbott Biotechnology Limited ("Abbott Biotech") has held a sublicense from Centocor, Inc. ("Centocor") under U.S. Patent No. 6,270,766 ("the '766 patent"). Kennedy lacks sufficient information or knowledge to know what Plaintiffs intend by the phrase "related intellectual property," and denies the remaining allegations of Paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. Paragraph 7 is a conclusion of law to which no response is required. To the extent that a response is required, Kennedy denies the allegations of Paragraph 1 of the Complaint.

8. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the allegation concerning the alleged payment of royalties under the '766 patent by Plaintiffs, as recited in Paragraph 8 of the Complaint, and on that basis denies that allegation. Kennedy denies the remaining allegations of Paragraph 8 of the Complaint.

9. Kennedy admits that on January 26, 2011 counsel for Kennedy sent a letter to Abbott Laboratories notifying Abbott Laboratories (Bermuda) Limited ("Abbott Bermuda") and

Abbott Biotech of the issuance of the '442 patent, but denies Plaintiffs' characterization of the content of that letter. Kennedy admits that Abbott Biotech's current royalty obligation under its sublicense from Centocor is unchanged by the issuance of the '442 patent, but lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations of Paragraph 9 of the Complaint, and on that basis denies those allegations.

10. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' past marketing and sales activities and future plans concerning HUMIRA®, as recited in Paragraph 10 of the Complaint, and on that basis denies those allegations, and denies the remaining allegations of Paragraph 10 of the Complaint.

11. Kennedy admits that, as a charitable trust, it sells no product of its own, but denies the remaining allegations of Paragraph 11 of the Complaint.

12. Kennedy admits that it has enforced its patents on several occasions when disputes have arisen. Kennedy admits that in 2010 it commenced a civil action for infringement of the '766 patent against UCB, and that in 2009 it commenced a civil action for infringement of the '766 patent against Amgen, Inc. and Wyeth, and that in 2008 it initiated an arbitration proceeding against Abbott Bermuda and Abbott Biotech concerning the non-payment and under-payment of royalties under their sublicense from Centocor, and denies the remaining allegations of Paragraph 12 of the Complaint.

13. Kennedy denies the allegations of Paragraph 13 of the Complaint.

14. Kennedy denies that its counsel sent a letter to Abbott Laboratories "demanding that Abbott pay royalties under the '442 patent," but admits the remaining allegations of Paragraph 14 of the Complaint.

15. Kennedy admits that a previous dispute with Abbott Bermuda and Abbott Biotech

concerning royalty payments was arbitrated in New York, but denies the remaining allegations of Paragraph 15 of the Complaint.

16. Kennedy admits that in October 2008, Kennedy initiated an arbitration proceeding against Abbott Bermuda and Abbott Biotech in New York concerning their non-payment and under-payment of royalties under their sublicense from Centocor; admits that Plaintiffs moved to have the arbitration award confirmed as a judgment by the U.S. District Court for the Southern District of New York, and that neither Centocor nor Kennedy opposed the confirmation of the arbitration award; admits that Centocor commenced a civil action in the Southern District of New York to attempt to stop the arbitration from proceeding (Centocor's motion for a preliminary injunction was denied); lacks information or knowledge sufficient to form a belief as to the truth of the allegations concerning the meeting in New York in November 2003, as recited in Paragraph 16 of the Complaint, and on that basis denies those allegations; and denies the remaining allegations of Paragraph 16 of the Complaint.

17. Kennedy admits the allegations of Paragraph 17 of the Complaint.

18. Kennedy admits that venue lies in this District, but denies the remaining allegations of Paragraph 18 of the Complaint.

FACTUAL BACKGROUND

19. Kennedy denies the allegations of Paragraph 19 of the Complaint, except Kennedy admits that it is the owner of the '766 patent, which was issued by the United States Patent & Trademark Office ("PTO") on August 7, 2001. The '766 patent is a public document that speaks for itself.

20. Kennedy admits that on or about January 1, 1992, the Charing Cross Sunley

Research Centre and the Kennedy Institute for Rheumatology entered a "Research and Licensing Agreement" with Centocor, Inc. (now Janssen Biotech, Inc., referred to as "Centocor") which, among other things, granted Centocor the right to grant sublicenses of the "Patent Rights," as defined in the Agreement. The "Research and Licensing Agreement" is a document which speaks for itself. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations of Paragraph 20 of the Complaint, and on that basis denies those allegations.

21. Kennedy admits that on July 29, 2004, Centocor and Kennedy entered into an amendment of the 1992 agreement, but denies the remaining allegations of Paragraph 21 of the Complaint. The 2004 amendment is a document which speaks for itself.

22. Kennedy lacks information or knowledge sufficient to form a belief as to the truth of the allegation as to what "Abbott and Centocor agreed," as recited in Paragraph 22 of the Complaint, and on that basis denies that allegation. Kennedy admits that in October 2008 this Court recognized that Kennedy is an intended third party beneficiary of the sublicense agreement between Centocor and Abbott Bermuda and Abbot Biotech.

23. Kennedy denies that it has been paid tens of millions of dollars in royalties under the '766 patent alone, and lacks information or knowledge sufficient to form a belief as to the truth of the allegations concerning in Paragraph 23 of the Complaint, and on that basis denies those allegations.

24. Kennedy admits the allegations of Paragraph 24 of the Complaint.

25. Kennedy admits that during prosecution of the '766 application, Centocor's counsel claimed the benefit of an earlier filing date, pursuant to 35 U.S.C. § 120, of U.S. patent application number 07/958,248, filed October 8, 1992, but denies the remaining allegations of

Paragraph 25 of the Complaint.

26. Kennedy admits the allegations of Paragraph 26 of the Complaint.

27. Kennedy admits the allegations of Paragraph 27 of the Complaint.

28. Kennedy admits that the quotation recited in Paragraph 28 of the Complaint is accurate, but otherwise denies the characterization of the quotation.

29. Kennedy admits that the quotation recited in Paragraph 29 of the Complaint is accurate but incomplete, admits that the quoted language was contained in a document filed in the PTO by Centocor's counsel in September 1999, but otherwise denies the characterization of the quotation.

30. Kennedy denies the allegations of Paragraph 30 of the Complaint.

31. Kennedy admits that the quotation recited in Paragraph 31 of the Complaint is accurate, but denies the remaining allegations of Paragraph 31 of the Complaint.

32. Kennedy admits that the '442 patent issued from U.S. patent application Serial No. 11/225,631 filed on September 12, 2005, but denies the remaining allegations of Paragraph 32 of the Complaint.

33. Kennedy denies the allegations of Paragraph 33 of the Complaint.

34. Kennedy admits that during prosecution of the '442 application, the benefit of a filing date of August 1, 1996 was claimed, but denies the remaining allegations of Paragraph 34 of the Complaint.

35. Kennedy admits the allegations of Paragraph 35 of the Complaint.

36. Kennedy admits that the '442 patent issued with 22 claims, but denies the remaining allegations of Paragraph 36 of the Complaint.

37. Kennedy denies the allegations of Paragraph 37 of the Complaint.

38. Kennedy admits that claim 14 of the '442 patent is accurately quoted in Paragraph 38 of the Complaint, but otherwise denies the allegations of Paragraph 38 of the Complaint.

39. Paragraph 39 is argument to which no response is required. To the extent that a response is required, Kennedy denies the allegations of Paragraph 39 of the Complaint.

40. Paragraph 40 is argument to which no response is required. To the extent that a response is required, Kennedy denies the allegations of Paragraph 40 of the Complaint, except admits that the quotation at the end of Paragraph 40 is accurate.

41. Kennedy denies the allegations of Paragraph 41 of the Complaint.

42. Paragraph 42 is a conclusion of law to which no response is required. To the extent that a response is required, Kennedy denies the allegations of Paragraph 42 of the Complaint.

COUNT I
(Declaratory Judgment of Invalidity of the '442 Patent

43. Kennedy repeats and realleges its responses to Paragraphs 1-42 herein.

44. Kennedy denies the allegations of Paragraph 44 of the Complaint.

45. Kennedy denies the allegations of Paragraph 45 of the Complaint.

46. Kennedy denies the allegations of Paragraph 46 of the Complaint.

AFFIRMATIVE DEFENSES

Kennedy hereby reserves any and all affirmative defenses as may be appropriate under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States and any other defense, at law or in equity, that may now exist or in the future be available based upon discovery and further investigation in this case.

First Affirmative Defense

The Complaint fails to state a claim against Kennedy upon which relief can be granted.

Second Affirmative Defense

Plaintiff Abbott Laboratories lacks standing to assert the claim it has asserted in this action.

Third Affirmative Defense

The doctrine of obviousness-type double patenting does not apply to the '442 patent because Kennedy has not received an unjust time-wise extension of its right to exclude others by the issuance of the '442 patent.

Fourth Affirmative Defense

The claims of the '442 Patent are valid, and are not invalid under the doctrine of nonstatutory obviousness-type double patenting because each claim of the '442 Patent is patentably distinct from, and not an obvious variant of, any claim of the '766 Patent.

Fifth Affirmative Defense

The Court lacks subject matter jurisdiction because there is no imminent or real case or controversy between the parties to support declaratory judgment jurisdiction.

COUNTERCLAIMS

Defendant and Counterclaim-Plaintiff Kennedy for its First Amended Counterclaims against Plaintiffs and Counterclaim-Defendants, hereby alleges as follows:

THE PARTIES

1. Counterclaim-Plaintiff The Mathilda and Terence Kennedy Institute of Rheumatology Trust is a British registered charity having a place of business at 65 Aspenlea Road, Hammersmith, London W6 8LH England ("Kennedy").

2. Counterclaim-Defendant Abbott Laboratories claims to be an Illinois corporation that has its United States corporate headquarters at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. On information and belief, Abbott Laboratories does business throughout the United States, including the State of New York.

3. Counterclaim-Defendant Abbott Biotechnology Limited claims to be a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda ("Abbott Biotech"). Counterclaim-Defendants claim that through intermediate companies, Abbott Biotechnology Limited is owned by Abbott Laboratories. (Abbott Laboratories, Abbott Biotech, and all related companies will be referred to individually and/or collectively as "Abbott," unless otherwise specified.)

4. On information and belief, since 2003, Abbott has marketed and sold in the United States and abroad the pharmaceutical drug HUMIRA®.

5. Counterclaim-Defendants have commenced this civil action for a declaration of invalidity of U.S. Patent No. 7,846,442 ("the '442 patent"), by filing a Complaint in this Court against Counterclaim-Plaintiff Kennedy. Counterclaim-Defendants' allegations, as sustained by

the Court, have created an actual controversy between the parties with respect to the validity and coverage of the '442 patent.

NATURE OF CLAIMS AND BASIS FOR JURISDICTION AND VENUE

6. These are counterclaims for a declaration that U.S. Patent No. 7,846,442 is not invalid, for a declaration that U.S. Patent No. 7,846,442 covers Abbott's HUMIRA® product as marketed by Abbott, for improper calculation of royalties, for damages for underpaid royalties, and for breach of contract.

7. This court has jurisdiction over the counterclaims based upon 28 U.S.C. §§ 1331, 1332(a)(2), 1338 and 1367.

8. There is complete diversity of citizenship between the parties, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

9. As a result of Counterclaim-Defendants' filing of this action, this Court has jurisdiction over the declaratory judgment counterclaims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. Venue is proper in this jurisdiction under 28 U.S.C. §§ 1391(b), (c) and (d).

11. Counterclaim-Defendants have availed themselves of the jurisdiction of this Court by commencing this action against Kennedy for a declaratory judgment.

FACTUAL BACKGROUND

12. Sir Marc Feldmann is an immunologist, and a professor at, and head of, the Kennedy Institute of Rheumatology ("Kennedy Institute") of the University of Oxford in England. Sir Marc graduated from the University of Melbourne in 1967 with a Bachelor of

Medicine, Bachelor of Surgery degree, and then earned a Ph.D. in Immunology at the Walter and Eliza Hall Institute of Medical Research in 1972 with Sir Gustav Nossal.

13. Sir Ravinder Nath Maini is an immunologist, and is an Emeritus Professor at the Kennedy Institute of the University of Oxford. Sir Ravinder received his bachelor's degree at Sidney Sussex College in Cambridge, England, and his MB Bchir degree (Bachelor of Medicine, Bachelor of Surgery) from Cambridge University.

14. Sirs Marc and Ravinder worked together at the Charing Cross Sunley Research Centre, which later merged with the Kennedy Institute. Sirs Marc and Ravinder collaborated to study rheumatoid arthritis, a clinically important autoimmune disease affecting a significant portion of the population.

15. In 2000, the Kennedy Institute became a part of the Faculty of Medicine at Imperial College, and in 2011 the Kennedy Institute moved from Imperial College to the Medical Sciences Division of the University of Oxford. Sirs Marc and Ravinder have been associated with the Kennedy Institute since 2000.

16. In autoimmune diseases, the immune system attacks and damages the body, leading to the disease of various tissues, such as the joints of patients suffering from rheumatoid arthritis. While at Sunley, Sirs Marc and Ravinder demonstrated that diseased joints have far more pro-inflammatory cytokines than normal, and identified one of these cytokines, Tumor Necrosis Factor Alpha, abbreviated as "TNFα," as having a critical role in rheumatoid arthritis.

17. TNFα inhibitors have become the therapy of choice for stopping the inflammatory and tissue-destructive pathways of rheumatoid arthritis and other autoimmune and inflammatory diseases.

18. Sirs Marc and Ravinder were knighted by the Queen of England for their research, and have shared many awards. In 2000, they were awarded the prestigious Crafoord Prize by the Royal Swedish Academy of Science. In 2003, the two were awarded the Albert Lasker Award for Clinical Medical Research (the "U.S. Nobel Prize"). In 2004, they were awarded the Cameron Prize for Therapeutics of University of Edinburgh. In 2008, Sirs Marc and Ravinder were awarded the Dr. Paul Janssen Award for Biomedical Research by Johnson & Johnson. In 2010, they were awarded the Ernst Schering Prize, one of the most prestigious German awards for scientists.

19. Sir Marc is a Fellow of the Royal College of Physicians and of the Royal College of Pathologists. He was elected a Fellow of several national Academies, the Academy of Medical Sciences, the Royal Society of London and is a Corresponding Member of Australian Academy of Science, and a Foreign Member of the National Academy of Sciences in this country. In 2007, Sir Marc was awarded the European Patent Office's "European Inventor of the Year" in the Lifetime Achievement Category. Sir Marc also was awarded the John Curtin Medal of the Australian National University.

20. Sir Ravinder is a Fellow of the Royal Society of Medicine, the Slovakian Rheumatology Society, and the Royal College of Physicians in London and Edinburgh. Sir Ravinder also has been awarded Honorary Fellowships of Sidney Sussex College and The British Society of Rheumatology. Sir Ravinder has received a Doctor Honoris Causa from the University René Descartes in Paris, and an Honorary Doctorate of Science from the University of Glasgow.

21. There are now five approved anti-TNFα drugs on the market in the U.S., including HUMIRA® (sold by Abbott), REMICADE (sold by Centocor), SIMPONI (sold by

Centocor), ENBREL (sold by Amgen/Pfizer) and CIMZIA (sold by UCB). These drugs have been used to treat millions of patients suffering from autoimmune diseases, such as rheumatoid arthritis.

KENNEDY'S PATENTS

22. The research of Sirs Marc and Ravinder led to the filing of several patent applications in the U.S. and abroad which together comprise a family of patents ("the Patent Family"). Kennedy has licensed the Patent Family for use by each of the pharmaceutical companies distributing the anti-TNFα drugs cited in the preceding paragraph.

23. Kennedy is the owner of all right, title and interest in and to U.S. Patent No. 6,270,766, granted August 7, 2001, entitled "Anti-TNF Antibodies and Methotrexate in the Treatment of Arthritis and Crohn's Disease" ("the '766 patent"). The '766 patent relates to treating arthritis and other diseases by co-administering methotrexate and an anti-tumor necrosis factor alpha antibody or fragment thereof ("anti-TNFα antibody") in a therapeutically effective amount. The '766 patent is valid and enforceable.

24. The '766 patent claims the benefit of the filing date of a U.S. patent application (Serial No. 07/958,248), which was filed October 8, 1992. This benefit claim was unnecessary because the disclosure that supports the claims of the '766 patent was not present in U.S. Serial No. 07/958,248, and was first disclosed in the application for the '766 patent, which was filed August 1, 1996.

25. The application for the '766 patent was filed thirteen months after implementation on June 8, 1995 of the Uruguay Round Agreement Act allowing the participation of the United States in the General Agreement on Tariffs and Trades ("GATT Uruguay Round"). The GATT Uruguay Round changed the term of U.S. patents. Prior to implementation of the GATT

Uruguay Round, the term of a U.S. patent was 17 years from the date of issuance. Under the GATT Uruguay Round, the term of a U.S. patent is 20 years from the earliest filing date of the application.

26. Under the GATT Uruguay Round, the '766 patent will expire on October 8, 2012. Because of the unnecessary benefit claim, the term of the '766 patent was shortened by almost four years from the term to which Kennedy would otherwise have been entitled.

27. Because of the four year shortening of the term described in the preceding paragraph, as well as PTO delays during five years of prosecution, the life of the '766 patent from its issuance to its expiration will be only 11 years and 2 months.

28. Kennedy also is the owner of all right, title and interest in and to U.S. Patent No. 7,846,442, granted December 7, 2010, entitled "Methods of Treating Rheumatoid Arthritis with an Anti-TNF-Alpha Antibodies and Methotrexate" ("the '442 patent"). The '442 patent claims a method of reducing or eliminating signs and symptoms in an individual with rheumatoid arthritis whose active disease is incompletely controlled despite already receiving methotrexate by adjunctively continuing methotrexate therapy while also administering a composition containing a specific type of anti-TNFα antibody at a specified dosage. The '442 patent is valid and enforceable.

29. The application for the '442 patent was filed September 12, 2005, and claims the benefit of the filing date of the application for the '766 patent, which was filed August 1, 1996. For patent applications filed on or after May 29, 2000, Congress amended the U.S. Patent Law so that the term of a patent is adjusted if the issuance of the patent is delayed due to the PTO. 35 U.S.C. § 154(b). The '766 patent, which was filed August 1, 1996, did not receive such a patent term adjustment.

30. Under the GATT Uruguay Round, without a patent term adjustment, the '442 patent would have expired on August 1, 2016, which is the same date that the '766 patent would have expired if the benefit claim had not been made. The term of the '442 patent was adjusted by adding 750 days because of delays caused by the PTO. As a result, the '442 patent will expire August 21, 2018.

31. The '442 patent will expire at the same time that the '766 patent would have expired (excluding the patent term adjustment to the '442 patent for PTO delays) if the unnecessary benefit claim had not been made. The '442 patent did not result in Kennedy receiving an unjust time-wise extension of its right to exclude others under the Patent Laws.

32. The '766 patent and the '442 patent are included in the Patent Family.

NOT OBVIOUS TO TRY, NO REASONABLE EXPECTATION OF SUCCESS AND SECONDAY CONSIDERATIONS, INCLUDING UNEXPECTED RESULTS

33. The adjunctive therapy recited in the claims of the '442 patent involves the continued administration of methotrexate to patients whose active disease is incompletely controlled despite already receiving methotrexate.

34. Methotrexate is toxic. It would not have been obvious to try continued methotrexate therapy for patients who already had failed treatment with methotrexate given its known toxicity.

35. The efficacy and toxicity of a combined therapy using two therapeutic agents (an anti-TNFα antibody and methotrexate) cannot be predicted on the basis of the efficacy and toxicity of the individual therapeutic agents. For at least this reason, the adjunctive therapy claimed in the '442 patent would not have had a reasonable expectation of success.

36. Combination therapy includes adjunctive, sequential and simultaneous therapies. Many combination therapies in general show no improved efficacy when compared to therapy utilizing only one of the treatments used in monotherapy. For at least this reason, the adjunctive therapy claimed in the '442 patent would not have had a reasonable expectation of success.

37. A clinical article published before the priority date of the application for the '442 patent stated that "[c]ombination therapy as it has been used in clinical trials is not a valuable therapeutic alternative for most patients with RA [rheumatoid arthritis]." For at least this reason, the adjunctive therapy claimed in the '442 patent would not have had a reasonable expectation of success.

38. As described in the specification of the '442 patent, patients who failed to respond to methotrexate therapy showed a remarkably high response rate when given adjunctive therapy, even after the disappearance of therapeutic levels of antibody. These results were unexpected.

39. In light of the uncertainty in the art at the time the invention was made, it was far from obvious that adjunctive therapy as recited in the claims of the '442 patent would provide the unexpected results that were obtained.

40. During prosecution of the application for the '442 patent in the PTO, the Patent Examiner rejected the claims under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of the '766 patent. In response to the rejections, Kennedy submitted arguments and evidence, demonstrating that the invention claimed in the '442 patent would not have been obvious from the invention claimed in the '766 patent, because, among other things, there was no reasonable expectation of success and there were unexpected results. The Examiner withdrew the obviousness-type double patenting rejection as well as other rejections, and the claims were allowed.

THE SUBLICENSE AGREEMENT

41. On or about January 1, 1992, the Kennedy Institute for Rheumatology and the Charing Cross Sunley Research Centre entered into a "Research and Licensing Agreement" with Centocor, Inc. ("the Kennedy/Centocor Agreement"), which grants Centocor exclusive rights, including the right to grant sublicenses, under the Patent Family. The Kennedy/Centocor Agreement is valid and subsisting.

42. On information and belief, on December 23, 2002, Centocor entered into a "Non-Exclusive License Agreement" with Abbott Laboratories (Bermuda) Limited ("Abbott Bermuda") and Abbott Biotech ("the Abbott/Centocor Agreement") which grants Abbott Bermuda and Abbott Biotech a sublicense under certain patents in the Patent Family. Upon information and belief, Centocor also received a cross-license from Abbott Bermuda and/or Abbott Biotech for patent rights owned by either or both of them. Kennedy is not a party to the Abbott/Centocor Agreement, but is an intended third party beneficiary. The Abbott/Centocor Agreement is valid and subsisting.

43. Abbott Laboratories is not a signatory to the Abbott/Centocor Agreement.

44. On or about July 29, 2004, Kennedy entered into an "Amendment No. 1 To Research and Licensing Agreement" with Centocor, which, among other things, permitted Abbott Bermuda and Abbott Biotech to make royalty payments under the Abbott/Centocor Agreement directly to Kennedy, rather than paying royalties to Centocor for payment over to Kennedy.

45. Since 2003, Kennedy has been paid royalties under the terms of the Abbott/Centocor Agreement based on marketing and sales of HUMIRA®, but such royalty payments always have been deficient.

46. On October 1, 2008, Kennedy initiated an arbitration proceeding against Abbott Bermuda and Abbott Biotech in New York as a third party beneficiary of the Abbott/Centocor Agreement regarding, *inter alia,* the amount of royalty payments owed to Kennedy. At that time, Abbott and Centocor already had agreed to arbitrate certain issues relating to the Abbott/Centocor Agreement.

47. On March 13, 2009, a neutral arbitrator ruled that Abbott had underpaid royalties owed to Kennedy by many millions of dollars ("Arbitration Award"). The Arbitration Award also set forth the required methodology for calculating royalties due to Kennedy under the Abbott/Centocor Agreement, which, at Abbott's suggestion, uses Wolters Kluwer Healthcare Immunology Patient Centric Data ("WK Data").

48. On March 27, 2009, Kennedy, Abbott Laboratories and Centocor agreed in writing to a clarification of the payment methodology for calculating royalties set forth in the Arbitration Award, and agreed to a procedure for quarterly royalties to be paid by Abbott in two stages: an initial payment, and a later adjusted payment ("the March 27, 2009 Letter Agreement").

49. On April 29, 2009, the Arbitration Award was confirmed by a Judgment of this Court (Civil Action No. 09-cv-3872 (DC)), at Abbott's request ("the SDNY Judgment"). Abbott and Kennedy are parties to the SDNY Judgment.

50. Since January 1, 2009 and continuing through the present, Abbott has continued to make royalty payments to Kennedy based on net sales of HUMIRA®, but its royalty payments have been deficient because, upon information and belief, Abbott has not adhered to the methodology for calculating royalties pursuant to the SDNY Judgment.

51. Kennedy has notified Abbott of the deficiency of Abbott's royalty payments, and

Abbott has not remedied or cured its underpayments.

52. Kennedy has been accepting Abbott's deficient royalty payments under protest.

53. Kennedy requested to see the data and computer program used by Abbott to calculate royalties, but Abbott refused to provide access to Kennedy.

54. Kennedy requested an audit of Abbott's books and records to determine Abbott's compliance with the SDNY Judgment, but Abbott has stated that Kennedy is not permitted to conduct such an audit.

55. Kennedy has not received any royalties for sales of HUMIRA® in Hong Kong, which sales are covered under Abbott's sublicense from Centocor and under Kennedy's patent rights in Hong Kong.

56. Upon information and belief, Abbott's sales of HUMIRA® were $6.5 billion in 2010, and are expected to reach over $8 billion in 2011. Of that substantial revenue, Abbott has paid less than 1% to Kennedy under its sublicense from Centocor, and has continually failed to pay the full amount owed.

COUNT I
DECLARATORY JUDGMENT OF PATENT VALIDITY

57. Kennedy repeats the allegations set forth in paragraphs 1 through 56 as if fully set forth herein.

58. The '442 patent is presumed to be valid. 35 U.S.C. § 282.

59. By filing and maintaining this declaratory judgment action, Counterclaim-Defendants have created a case or controversy as to the validity of the '442 patent under the judicially-created doctrine of obviousness-type double patenting.

60. The doctrine of obviousness-type double patenting does not apply to the '442

patent because Kennedy has not received an unjust time-wise extension of its right to exclude others by the issuance of the '442 patent.

61. The '442 patent is a continuation of the '766 patent.

62. No claim of the '442 patent is obvious over any claim of the '766 patent, under the judicially-created doctrine of obviousness-type double patenting, as determined by the PTO during prosecution.

63. Abbott has not alleged any other basis for asserting that any claim of the '442 patent is invalid.

64. The claims of the '442 patent should be declared not invalid by the Court.

COUNT II
DAMAGES FOR UNDERPAID ROYALTIES

65. Kennedy repeats the allegations set forth in paragraphs 1 through 64 as if fully set forth herein.

66. Abbott is required to pay royalties to Kennedy for the marketing and sale of HUMIRA®.

67. The SDNY Judgment requires Abbott to pay royalties to Kennedy and to use a specific methodology for quantifying the "Co-Administration Product" on which royalties are to be paid to Kennedy for Abbott's marketing and sale of HUMIRA®.

68. The SDNY Judgment is final, has not been appealed, and is in full force and effect.

69. Kennedy and Abbott are parties to the SDNY Judgment.

70. Under the March 27, 2009 Letter Agreement, Abbott is required to use the methodology specified in the Arbitration Award and confirmed by the SDNY Judgment for

calculating royalties owed to Kennedy for Abbott's marketing and sale of HUMIRA® in the U.S. and Europe.

71. The March 27, 2009 Letter Agreement is in full force and effect.

72. Kennedy and Abbott are parties to the March 27, 2009 Letter Agreement.

73. Upon information and belief, Abbott has not used the specific, required methodology for calculating royalties to be paid to Kennedy for Abbott's marketing and sale of HUMIRA® in the U.S. and Europe, and, as a result, Abbott has underpaid the royalties due to Kennedy.

74. By underpaying the royalties due to Kennedy for Abbott's marketing and sales of HUMIRA® in the U.S. and Europe, Abbott has not complied with its financial obligations to Kennedy.

75. Abbott owes Kennedy substantial amounts of underpaid royalties from January 1, 2009 to date.

76. Kennedy has been damaged by Abbott's underpayment of royalties for its marketing and sales of HUMIRA® in the U.S. and Europe in an amount to be determined at trial.

COUNT III
DECLARATORY JUDGMENT OF PATENT CLAIM COVERAGE

77. Kennedy repeats the allegations set forth in paragraphs 1 through 76 as if fully set forth herein.

78. Abbott claims that it has been marketing and selling HUMIRA® in the United States since 2003 and has no plans to cease such activities.

79. Abbott claims that it would risk a suit for infringement of the '442 patent if it continued its marketing and sales of HUMIRA®, but terminated its sublicense agreement with Centocor or otherwise did not make royalty payments to Kennedy under the '442 patent after

October 2012.

80. Abbott claims that if Kennedy demands payment from Abbott under the '442 patent, Abbott will be required to pay millions of dollars in royalties to Kennedy for sales of HUMIRA® for use with methotrexate to treat rheumatoid arthritis.

81. Abbott's claim for a declaratory judgment of invalidity of the '442 patent is predicated on Abbott's owing royalties to Kennedy under the '442 patent for Abbott's ongoing marketing and sales of HUMIRA®.

82. This Court has held that "'it is … virtually certain that the ['442 patent] will apply to the plaintiffs' in October 2012, if it is not found to be invalid." (D.I. 25 at 9.)

83. The '442 patent and each and every claim thereof is valid and enforceable.

84. Abbott's ongoing or planned activity of continuing its sales of HUMIRA® for adjunctive use with methotrexate to treat rheumatoid arthritis falls within the scope of at least one claim of the '442 patent.

85. The Court should declare that Abbott's marketing and sale of HUMIRA® for adjunctive therapy with methotrexate comes within the scope of at least one valid claim of the '442 patent.

COUNT IV
DECLARATORY JUDGMENT OF ABBOTT'S FAILURE TO COMPLY WITH FEDERAL JUDGMENT

86. Kennedy repeats the allegations set forth in paragraphs 1 through 85 as if fully set forth herein.

87. There is an actual controversy between the parties concerning Abbott's failure to comply with a valid federal judgment of this Court.

88. By the acts alleged herein, Abbott has failed to comply with the SDNY Judgment.

89. Unless and until the obligations of Abbott are determined by this Court, Abbott will continue its failure to comply with the SDNY Judgment.

90. Kennedy is entitled to a declaratory judgment that Abbott has failed to comply with the SDNY Judgment.

COUNT V
BREACH OF MARCH 27, 2009 LETTER AGREEMENT

91. Kennedy repeats the allegations set forth in paragraphs 1 through 90 as if fully set forth herein.

92. The March 27, 2009 Letter Agreement is a valid and enforceable contract between Abbott and Kennedy.

93. The consideration of the March 27, 2009 Letter Agreement is, at least, Abbott's ability to continue its ongoing marketing and sales of the drug HUMIRA®.

94. In calculating royalties owed to Kennedy for Abbott's marketing and sale of HUMIRA®, Abbott has failed to use the methodology set forth in the Arbitration Award confirmed by the SDNY Judgment each time Abbott pays royalties for any given quarter, as required under the March 27, 2009 Letter Agreement.

95. The procedure for paying royalties set forth in the March 27, 2009 Letter Agreement is a material term of the agreement.

96. By failing to follow the required procedure for paying royalties owed to Kennedy for Abbott's marketing and sale of HUMIRA®, which includes using the methodology for calculating royalties in the Arbitration Award confirmed by the SDNY Judgment, and thereby underpaying royalties for U.S. and European sales, Abbott has materially breached the March 27, 2009 Letter Agreement.

97. By reason of Abbott's breach of the March 27, 2009 Letter Agreement, Kennedy has been damaged in an amount to be determined at trial.

98. In addition, Abbott's apparent intent to fail to fulfill its obligations in the future creates a continuing harm for which Kennedy is entitled to specific performance directing Abbott to follow the procedure for paying royalties owed to Kennedy.

WHEREFORE, Kennedy prays for judgment as follows:

A. That Abbott's Complaint be dismissed with prejudice;

B. Declaring that United States Patent No. 7,846,442, and each and every claim thereof, is not invalid;

C. Declaring that Abbott's ongoing, continued sales of HUMIRA® for adjunctive use with methotrexate to treat rheumatoid arthritis, falls within the scope of at least one valid claim of the '442 patent;

D. Declaring the Abbott has failed to comply with the Judgment of the United States District Court for the Southern District of New York in *Abbott Biotechnology Ltd. et al. v. The Mathilda and Terence Kennedy Institute of Rheumatology Trust et al.*, Civil Action No. 09 Civ. 3872 (DC), dated April 30, 2009 ("the SDNY Judgment);

E. Awarding Kennedy in excess of $6,000,000 in underpaid royalties plus interest;

F. A permanent injunction requiring Abbott, its successor and assigns, to comply with the March 27, 2009 Letter Agreement;

G. Awarding Kennedy its reasonable attorneys' fees and costs because of the exceptional nature of this case, pursuant to 35 U.S.C. § 285, and/or under any other statute or law cited in the Counterclaims; and

H. Granting Kennedy such other and further relief as may be just and proper under the circumstances, facts and evidence in this case.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38, Fed. R. Civ. P., Counterclaim-Plaintiff The Mathilda and Terence Kennedy Institute of Rheumatology Trust hereby demands a trial by jury in this action on all claims and issues triable of right by a jury.

Respectfully submitted,
COOPER & DUNHAM LLP

/s/ John P. White

By: _____

Dated: January 9, 2012

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